

PATENT
Attorney Docket No. 013306-5001-02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Fanie Retief VAN HEERDEN *et al.*)
Application No.: Unassigned)
(Divisional of Copending Application No. 09/402,962))
Filed: Concurrently with Divisional Filing)
Title: Pharmaceutical Compositions Having)
Appetite Suppressant Activity)
Examiner: Unassigned
Group Art Unit: Unassigned

Commissioner for Patents and Trademarks
Washington, D.C.

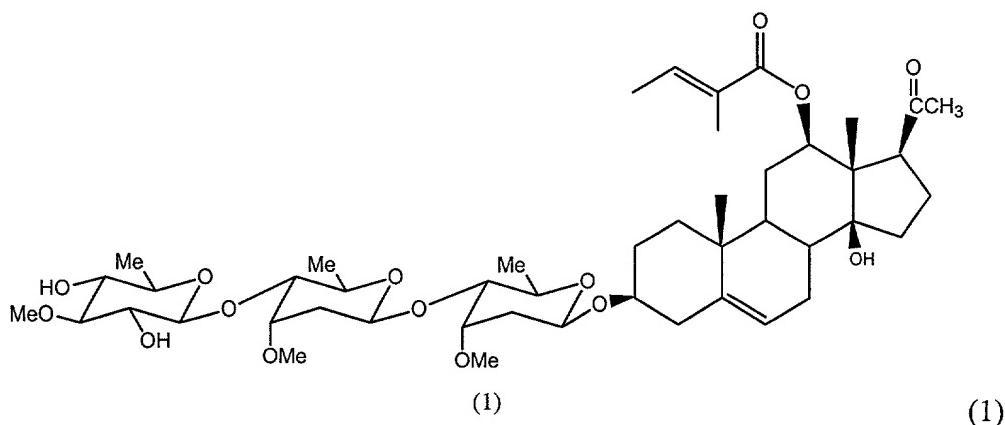
Sir:

PRELIMINARY AMENDMENT

Prior to the examination of the above-identified application on the merits, please amend
the application as follows:

IN THE ABSTRACT:

ABSTRACT OF THE DISCLOSURE



A pharmaceutical composition which contains an extract obtainable from a plant of the genus *Trichocualon* or *Hoodia* containing an appetite suppressant agent having the formula (1).

A process for obtaining the extract and a process for synthesizing compound (1) and its analogues and derivatives is also provided. The invention also extends to the use of such extracts and compound (1) and its analogues for the manufacture of medicaments having appetite suppressant activity. The invention further provides novel intermediates for the synthesis of compound (1).

IN THE SPECIFICATION

On page 1, line 3, insert:

-- This application is a Divisional of copending Application No. 09/402,962 filed on October 13, 1999, which is the U.S. national phase of PCT International Application No. PCT/GB98/01100, filed April 15, 1998, which claims priority to South African application No. 97/3201, filed April 15, 1997.--

IN THE CLAIMS:

Please cancel claims 25-121 without waiver, disclaimer or prejudice.

Please amend the claims as follows:

1. (Amended) A process for preparing an extract of a plant of the genus *Trichocaulon* or of the genus *Hoodia*, the extract comprising an appetite suppressant agent, the process including the steps of treating plant material with a solvent to extract a fraction having appetite suppressant activity, separating the extraction solution from the rest of the plant material, removing the solvent from the extraction solution and recovering the extract.
3. (Amended) A process as claimed in claim 1 which includes the step of concentrating the active agent in the extracted material by further extraction with a solvent.
4. (Amended) A process as claimed in claim 1, wherein the solvent in the solvent extraction step or steps is one or more of methylene chloride, water, methanol, hexane, ethyl acetate or mixtures thereof.

5. (Amended) A process as claimed in claim 1 which includes the step of concentrating the active agent in the extracted material by chromatographic separation.
7. (Amended) A process as claimed in claim 5 which includes carrying out the chromatographic separation on a column, collecting the eluate in fractions from the column, evaluating the fractions to determine their appetite suppressant activity, and selecting the at least one fraction containing the appetite suppressant agent.
8. (Amended) A process as claimed in claim 1 wherein the extract is processed to form a free-flowing powder.
9. (Amended) An extract comprising an appetite suppressant agent when produced by a process as claimed in claim 1.
12. (Amended) A composition as claimed in claim 11 which is prepared in unit dosage form.
15. (Amended) A method of suppressing an appetite by administering to a human or animal an effective dosage of a composition as claimed in claim 10.
16. (Amended) A process for preparing an extract of a plant of the genus *Trichocaulon* or of the genus *Hoodia*, the extract comprising an appetite suppressant agent, the process including the steps of pressing plant material to separate sap from solid plant material and recovering the sap free of the solid plant material to form the extract.
18. (Amended) An extract comprising an appetite suppressant agent when produced by a process as claimed in claim 16.

21. (Amended) A composition as claimed in claim 20 which is prepared in unit dosage form.

24. (Amended) A method of suppressing an appetite by administering to a human or animal an effective dosage of a composition as claimed in claim 19.

1-WA/1694430.1

REMARKS

Claims 25-121 have been cancelled without waiver, disclaimer or prejudice. Claims 1, 3, 4, 5, 7, 8, 9, 12, 15, 16, 18, 21 and 24 have been amended to correct multiple dependencies. Support for the amendments to the claims can be found in the claims as originally filed and throughout the specification. No new matter has been added by this Preliminary Amendment. Upon entry of this Preliminary Amendment, claims 1-24 will be pending.

EXCEPT for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-0310. This paragraph is intended to be a **CONSTRUCTION PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,
MORGAN, LEWIS & BOCKIUS LLP

Date: February 13, 2002

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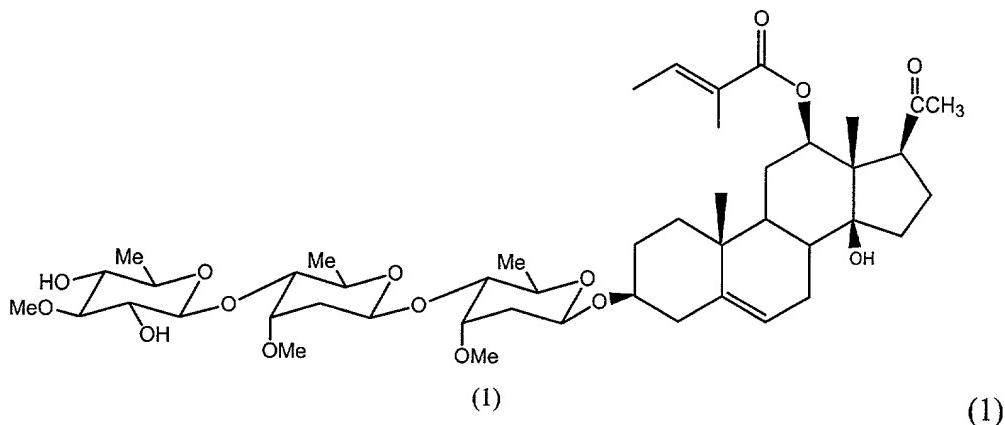
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APPENDIX
VERSION WITH MARKINGS TO SHOW CHANGES

I. IN THE ABSTRACT

ABSTRACT OF THE DISCLOSURE



A pharmaceutical composition which contains an extract obtainable from a plant of the genus *Trichocualon* or *Hoodia* containing an appetite suppressant agent having the formula (1). A process for obtaining the extract and a process for synthesizing compound (1) and its analogues and derivatives is also provided. The invention also extends to the use of such extracts and compound (1) and its analogues for the manufacture of medicaments having appetite suppressant activity. The invention further provides novel intermediates for the synthesis of compound (1).

II. IN THE SPECIFICATION

On page 1, line 3, insert:

--This application is a Divisional of copending Application No. 09/402,962 filed on October 13, 1999, which is the U.S. national phase of PCT International Application No. PCT/GB98/01100, filed April 15, 1998, which claims priority to South African application No. 97/3201, filed April 15, 1997.--

III. IN THE CLAIMS

1. (Amended) A process for preparing an extract of a plant of the genus *Trichocaulon* or of the genus *Hoodia*, the extract comprising an appetite suppressant agent, the process including the steps of treating ~~collected~~ plant material with a solvent to extract a fraction having appetite suppressant activity, separating the extraction solution from the rest of the plant material, removing the solvent from the extraction solution and recovering the extract.

3. (Amended) A process as claimed in claim 1 ~~or claim 2~~ which includes the step of concentrating the active agent in the extracted material by further extraction with a solvent.

4. (Amended) A process as claimed in claim 1, ~~claim 2, or claim 3~~, wherein the solvent in the solvent extraction step or steps is one or more of methylene chloride, water, methanol, hexane, ethyl acetate or mixtures thereof.

5. (Amended) A process as claimed in claim 1 ~~any one of claims 1 to 4 inclusive~~ which includes the step of concentrating the active agent in the extracted material by chromatographic separation.

7. (Amended) A process as claimed in claim 5 ~~or claim 6~~ which includes carrying out the chromatographic separation on a column, collecting the eluate in fractions from the column, evaluating the fractions to determine their appetite suppressant activity, and selecting the at least one fraction containing the appetite suppressant agent.

8. (Amended) A process as claimed in claim 1 ~~any of the preceding claims~~ wherein the extract is processed to form a free-flowing powder.

9. (Amended) An extract comprising an appetite suppressant agent when produced by a process as claimed in claim 1 ~~any of the preceding claims~~.

12. (Amended) A composition as claimed in ~~claim 10 or~~ claim 11 which is prepared in unit dosage form.
15. (Amended) A method of suppressing an appetite by administering to a human or animal an effective dosage of a composition as claimed in claim 10, ~~claim 11, or~~ claim 12.
16. (Amended) A process for preparing an extract of a plant of the genus *Trichocaulon* or of the genus *Hoodia*, the extract comprising an appetite suppressant agent, the process including the steps of pressing ~~collected~~ plant material to separate sap from solid plant material and recovering the sap free of the solid plant material to form the extract.
18. (Amended) An extract comprising an appetite suppressant agent when produced by a process as claimed in claim 16 ~~or~~ claim 17.
21. (Amended) A composition as claimed in ~~claim 19 or~~ claim 20 which is prepared in unit dosage form.
24. (Amended) A method of suppressing an appetite by administering to a human or animal an effective dosage of a composition as claimed in claim 19, ~~claim 20, or~~ claim 21.